

REMARKS

This is in response to the Office Action of March 13, 2009. Claims 1-6 are cancelled, without prejudice. Claim 7 is amended to recite formal process steps, as requested by the Examiner. New claims 10-15 are based upon such disclosure as that in the last full paragraph on page 33 of the specification. New claims 16 and 17 are based upon such disclosure as that in the last full paragraph on page 39 of the specification. No new matter is introduced by this Amendment. Claims 7-17 are pending in the application.

Claims 1-9 were rejected under the second paragraph of 35 U.S.C. § 112 as failing to define the invention properly. Office Action, page 2. This ground of rejection is moot with respect to claims 1-6. The objection to claims 7-9 – regarding the incompleteness of the recitation of process steps therein – is obviated by the present Amendment. It is respectfully submitted that claims 7-17 currently pending in this application fully comply with the requirements of the statute.

Claims 1-9 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US 5,472,954 (Lofstsson) in view of EP 1 380 579 (Mizui). Office Action, pages 2-3. The rejection is respectfully traversed.

The Mizui reference shows a macrolide compound which may be produced by the novel method of the present invention. However, the presently claimed method is neither taught by nor obvious from the Mizui and Lofstsson references.

As indicated e.g. in lines 12-15 of column 1, Lofstsson shows that the solubility and stabilization of unstable drugs may be improved with cyclodextrin and a polymer (“The present invention relates to the use of certain polymers in the preparation of cyclodextrin-drug complexes as a means for increasing the solubilizing and stabilizing effects of cyclodextrin derivatives on drugs”). Included in the extensive listing of drugs mentioned by Lofstsson are “macrolide antibiotics, such as erythromycin, josamycin, rosamycin, tylosin, troleandomycin and spiramycin.” Column 10, lines 51-53.

All of the macrolide drugs to which Loftsson refers are very difficult to dissolve in water. For instance, the Merck Index reports the following solubilities:

Tylosin	5 mg/ml
Erythromycin	~2 mg/ml
Josamycin	practically insoluble in water
Troleandomycin	solubility in water <0.1 g/100 ml
Spiramycin	slightly soluble in water

Accordingly, a person of ordinary skill in the art would understand that the concern with respect to the macrolide compounds mentioned by Loftsson is to improve their solubility, not their stability.

No test examples of these macrolide compounds are found in Loftsson. Nothing in the Loftsson disclosure refers to – much less supplies data relevant to – improved stability (or solubility) of the macrolide compounds.

In any event, moreover, all of the macrolide compounds which are the subject of the Loftsson disclosure have 14- or 16-membered rings. The macrolide compounds of the present invention have 12-membered rings. A person of ordinary skill in the art would not expect cyclodextrins to have the same or similar functions in macrolide compounds having different rings and different side chains from one another.

In summary, a person of ordinary skill in the art would not apply the Loftsson teachings to the macrolide compounds recited in claims 7-17 of the present application expecting to improve the stability thereof. It is only by impermissible hindsight – derived from Applicants' disclosure – that the cyclodextrin treatment of Loftsson would be combined with the macrolide compounds of Mizui. The rejection of record is not sustainable.


Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Richard Gallagher, Reg. No.

28,781, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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